



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1242]

Content and Format of Abbreviated 510(k)s for Early Growth Response 1 Gene Fluorescence In-Situ Hybridization Test System for Specimen Characterization Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices." This guidance provides industry and Agency staff with recommendations for the suggested format and content of an abbreviated 510(k) submission for EGR1 gene FISH test system for specimen characterization devices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1)

Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Shyam Kalavar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5568, Silver Spring, MD 20993-0002, 301-796-6807.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

This guidance document was developed to provide industry and Agency staff with recommendations for the suggested format and content of an abbreviated 510(k) submission for EGR1 gene FISH test system for specimen characterization devices and recommendations for addressing certain labeling issues relevant to the review process specific to these devices. An EGR1 gene FISH test system for specimen characterization is a device intended to detect the EGR1 probe target on chromosome 5q in bone marrow specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The assay results are intended to be interpreted only by a qualified pathologist or cytogeneticist. These devices do not include automated systems that directly report results without review and interpretation by a qualified pathologist or

cytogeneticist. These devices also do not include any device intended for use to select patient therapy, predict patient response to therapy, or to screen for disease as well as any device with a claim for a particular diagnosis, prognosis, and monitoring or risk assessment.

In the Federal Register of September 26, 2014 (79 FR 57939), the Agency issued the draft guidance entitled "Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices." The Agency received no comments on the draft guidance dated September 26, 2014.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Content and Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

## IV. Paperwork Reduction Act of 1995

This guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The

collections of information in 21 CFR part 807, subpart E, are currently approved under OMB control number 0910-0120 and the collections of information in 21 CFR part 809.10 are currently approved under 0910-0485.

#### V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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